

March 30, 1999

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**Susan Wagener
1046 Wellington Avenue
Libertyville, IL 60048**

**Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane, rm. 1061
Rockville, MD**

Subject: FDA-Docket No.98N-1265

To whom it may concern:

I have Celiac Disease, a non-contagious auto-immune condition that causes me to become ill if I eat any thing containing or derived from wheat, oats, barley, rye or malt.

Many over the counter and prescription medications contain ingredients which are harmful to me, including excipients, such as stabilizers, preservatives, colorings, flavorings, sweeteners, binders, dilutants, disintegrants, lubricants, coatings, additives and inert agents. If I need an over the counter or prescription medication I must do extensive research to see if it contains anything harmful to me. Many times there isn't a product available commercially and as a result, I must have a product custom made. Stokes Pharmacy in New Jersey is one place where I can get a custom replacement for a product that would otherwise be harmful to me.

If the subject restriction were implemented, a safe source of medications will be denied to me and the other thousands of people with my dietary restrictions or similar restrictions. Currently, Stokes Pharmacy is the ONLY place in the country I would trust to do my compounding as they truly understand celiac disease.

As you might imagine, life is very difficult already for anyone dealing

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with celiac disease. Your very careful consideration of the negative ramifications this restriction would impose in many, many people's lives would be greatly appreciated.

Sincerely,

Susan Wagener

Wagener
1046 Wellington Ave
Libertyville, IL 60048



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5630 Fishers Lane, Rm. 061
Rockville, MD 20852

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